

Kinser, Robin D.

From: Kinser, Robin D.
Sent: Tuesday, August 06, 2002 12:22 PM
To: Feng, Shixia
Cc: Kinser, Robin D.
Subject: RE: Review on Laboratory Comparison

Hi Shixia--

I have reviewed your presentation, and think you have been very thorough in your treatment. I do have a few comments and typos to mention. Please call me if you would like to discuss these thoughts:

- I don't see that you have included Qiwei's comments on the inappropriateness of regression analysis for these data. Even if that is what analytical chemists customarily do, I think you should point it that it appears to be an incorrect approach from the statistician's perspective. I have learned over the years that analysts have at times mis-used or ignored statistical science, and have much to learn from it.
- I woould like to see a specific "disclaimer" under the FDA bullet that this was not the case. We have documented somewhere, decided before the conduct of any analyses, that in the event of a different results being generated by Covance and INBIFO the Covance results would still be used. The Pilot TES is not a case where sample studies were conducted at more than one site.
- It might be helpful on the "data-rich" or "megabyte" slides (interspersed between p. 19 and p. 29) to highlight some of the lines to direct the viewer to the point you want to make. For example, that one ABP point where the difference is enormous could be highlighted.
- On slide 28 the slide title and the titles on the graphs are in disagreement (cotinine or 3-trans-hydroxycotinine?)
- Slide 31--I think "too short" or "too brief" of "incomplete" are better than "over-abbreviated".
- Slide 31--where you recommend a regression line--is a good place to bring up Qiwei's points against that approach.
- This line on slide 32 "**Since there is no statistically significant difference between the two labs, I don't have any objection to the use of the data generated by Covance.**" needs some re-consideration. It sounds as though that what Covance did in data analysis is correct if it tells you what you want to hear.
- Not for your talk, but because I want to know--what changes in internal standard and method for ABP do you propose?

I think that's all. Call me if you want to talk.

--Robin

----Original Message----

From: Feng, Shixia
Sent: Tuesday, August 06, 2002 8:49 AM
To: Kinser, Robin D.
Cc: Feng, Shixia
Subject: Review on Laboratory Comparison

Dear Robin,

I have finally finished putting together this presentation for tomorrow. Sorry for the delay. I had trouble opening the Covance's report which caused some delay. Please feel free to make changes.

Shixia

<< File: Lab Comparison.ppt >>

P.S. I am working on the filter part too but I have not been successful in opening the Covance's file that contains the filter information.